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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/543,144	STREEKSTRA, HUGO	
	Examiner	Art Unit	
	HAMID R. BADR	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/28/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 11/28/2008 is acknowledged.

Claims 1-25 are being considered on the merits.

Objection to Claims

Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 23 is objected to for the range of cations. Claim 23 depends on claim 22 which limits the amount of cation to more than 1g. However, claim 23 limits the amount of cation to "between 1g and 50g". Correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation in claims 1, 8, 11, 14, and 16 of "for improving the uptake of essential cations" is not supported by the specification.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claims 22 and 23 are indefinite for amount of the cation bound to phytate. It is not clear how much cation is bound by how much phytate.

2. Claim 24 is indefinite for "comprises and less than 99 g of phytate per 100 g essential cation bound to phytate". It is not clear what is meant by this phrase. It is unclear what the applicant regards as the invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1, 4-7, 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Sabin (US 5,217,959; hereinafter R1).

5. R1 discloses a composition and method of making the composition in which the active ingredient is a phytic acid, a mixed phytate salt (col. 4, lines 30-35). The

composition may contain extracellular phytase or other acid phosphatases or combination of enzymes (Col. 4, lines 64-68).

6. R1 discloses the cations to be sodium, magnesium, potassium, zinc, iron and the like (Col. 4, lines 43-46).

7. R1 discloses that once the composition is orally administered, the phytase contained in the composition will assist in hydrolyzing the phosphate groups (col. 6, lines 3-9).

8. R1 teaches that the composition may contain conventional excipients such as citric acid. (Col. 5, lines 40-45). Citric acid is known in the art to act as both chelating agent and antioxidant.

9. R1 discloses the use of phytase to assist in the hydrolysis of phytate. Given that any cations bound to phytates either naturally or through the administration of the composition will be released due to phytase, the increase in availability of the essential cation will be inherent in the functionality of the composition. The limitation of claim 10 is met.

10. R1 teaches that the phytic acid or phytate may be absorbed into or adsorbed onto a solid carrier to facilitate the administration. These compounds may be formulated into a starch powder or dextrin (Col. 5, lines 1-6).

11. Given that R1 discloses preparation as presently claimed, it is clear that when the preparation is present in the intestinal tract, essential cations would inherently be released from the phytate.

12. Given that R1 discloses preparation identical to that presently claimed, it is clear that the preparation would inherently improve the uptake of cations as presently claimed.

13. Claims 1, 4-7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanson (US 2,834,678; hereinafter R2).

14. R2 discloses a dietary supplement the production and utilization of phytin (calcium, magnesium and potassium phytates) (Col. 1, lines 36-40).

15. R2 teaches to combine a rich source of phosphatase enzymes with phytin or other phytates in order that hydrolysis may occur in the digestive tract and the dietary constituents may be easily assimilated (Col. 1, lines 48-52).

16. R2 teaches that other phytates may be produced by acidifying phytin to phytic acid and then combining with other metallic salts such as copper chloride. (Col. 2, lines 37-39).

17. R2 gives the details of making the preparation in the form of tablets (Col. 3, lines 65 to Col. 4 line 16).

18. R2 discloses the use of phosphatase (phytase) (Col. 1, lines 44-47) to assist in the hydrolysis of phytin and phytate. Given that any cations bound to phytin or phytates either naturally or through the administration of the composition will be released due to phosphatase (phytase), the increase in availability of the essential cation will be inherent in the functionality of the composition. The limitation of claim 10 is met.

19. R2 teaches using anti-oxidants such as tocopherols in the formulation (Col. 3, line 22).

20. Given that R2 discloses preparation identical to that presently claimed, it is clear that the preparation would inherently improve the uptake of cations as presently claimed.

21. Claims 14-15, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Beudeker (WO 02/054881; hereinafter R3).

22. R3 discloses foods in which phytase may be incorporated. The foods rich in phytic acid or phytates such as bread, cakes, pastries breakfast cereals or crackers. These foods may also be enriched in minerals, in particular in calcium, zinc, and/or iron. (page 2, lines 28-32).

23. Given that R3 discloses preparation identical to that presently claimed, it is clear that the preparation would inherently improve the uptake of cations as presently claimed.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. Claims 2-3, 8-9, 14-17, and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabin (US 5,217,959; hereinafter R1) in view of Beudeker (WO 02/054881; hereinafter R3).

26. The disclosure of R1 is hereby incorporated by reference as outlined above in paragraphs 5-11.

27. While R1 does not disclose the activity of phytase per gram phytate as presently claimed, it is obvious to those of ordinary skill in the art, that the amount of phytase in the preparation should be enough to hydrolyze all the added/included phytate to make sure that the essential minerals will be bioavailable. Given the formula weight and chemical structure of phytic acid, maximum amount of cations e.g. copper or iron etc. may be calculated per 100 g phytic acid or the amount of phytic acid required to deliver 100 g of cations may be calculated by those of skill in the art and would overlap that presently claimed.

28. R1 is silent regarding using the composition in foods or drinks.

29. R3 discloses foods and drinks that comprise phytase (page 2, line 11).

30. R3 discloses foods rich in phytic acid or phytates such as bread, cakes, pastries breakfast cereals or crackers. The foods may also be enriched in minerals, in particular in calcium, zinc, and/or iron. (page 2, lines 28-32).

31. R3 discloses that milk is a suitable means for delivering this enzyme to humans using milk as functional food enriched with minerals and phytase (page 4, lines 9-11). Foods such as cheeses, yoghurts, milk shakes, creams and desserts may also be used and delivery systems (Page 4, lines 12-13). Given that phytase will hydrolyze any phytic

acid and/or phytates, the essential minerals in milk or foods enriched with minerals will not be bound by phytic acid or phytates naturally present in the foods and will be biologically available.

32. R3 discloses that the food or drink of the invention will comprise phytase at a concentration of from 50-10000 FTU/kg. Given that one phytase unit is defined as the amount of enzyme which liberates on micromole of phosphate per minute from 1mM Na-phytate at pH 5.5 at 37C (Page 5, third paragraph), the amount of phytase required for certain amount of phytate in a given food may be calculated by those skilled in the art.

33. Given that R3 discloses milk as a delivery system for phytase, it is obvious to those of ordinary skill in the art that soymilk (proteinaceous liquid) may similarly comprise phytase in order to hydrolyze the natural phytin or phytates in the milk. The hydrolysis of phytin and/or phytates will further help increase the bioavailability of minerals in the milk and/or in the foods consumed with the milk.

34. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use the teachings of R1 and make foods and drinks comprising phytase as taught by R3. One would have done so to enrich foods and drinks with essential minerals or to take advantage of naturally occurring minerals. Since the phytase contained in such foods will hydrolyze the phytates, the bioavailability of such minerals will increase. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in making foods and drinks containing phytase.

35. Claims 11-13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabin (US 5,217,959; hereinafter R1) in view of Takabe et al. (US 2002/0012985; hereinafter R4) and Steinkraus (1996; hereinafter R5).

36. The disclosure by R1 is hereby incorporated by reference as outlined above in paragraphs 5-11.

37. R1 is silent regarding a condiment such as soy sauce comprising an active phytase.

38. R4 discloses that *Aspergillus oryzae* (koji mold) produces phytase and phosphatase when grown on defatted soybeans. The phytase enzyme will decompose and reduce the phytic acid contained in soybean [0055 and 0057].

39. R4 is does not directly mention soy sauce as a source of phytase.

40. R5 gives details of a process for making soy sauce. In that process, *Aspergillus oryzae* is added to cooked soybeans to be processed further to soy sauce. Therefore, soy sauce will intrinsically contain phytase.

41. It would have been obvious to one of ordinary skill in the art, to add essential minerals in the form of phytate to the raw materials for soy sauce which upon fermentation by the koji mold, will develop phytase in the soy sauce. Such a soy sauce will contain beneficial minerals which are bioavailable since the binding phytates will be hydrolyzed by phytase in soy sauce.

Response to Arguments

Applicant's arguments have been thoroughly reviewed. However, these arguments do not deem persuasive for the following reasons:

1. Applicant argues that Sabin (US 5,217,959) (R1) relates to the use of phosphates as active ingredients which can be used to treat MS.

a. By taking a closer look at R1, it is clear that it teaches the use of phytates which will carry cations such as magnesium, zinc, ferric, ferrous etc. Due to the chemical structure of phytic acid, diavalent or trivalent cations can be bound by the molecule. R1 then teaches that phytic acid or phytate can be administered with extracellular phytase. The essential cations being carried as phytate, will then be released upon hydrolysis of phytate resulting in the uptake of these cations. Therefore, R1 anticipates the composition of phytase and phytate containing essential cations.

2. Applicant argues that R1 teaches of using phytic acid alone without counterions and that R1 also teaches using sodium or potassium which are not essential cations.

a. R1 clearly teaches the use of phytic acid, a mixed counterion phytate salt or an isomer or hydrolysate of phytic acid or mixed counterion phytate salt. (Please see col. 4, lines 30-35). R1 also teaches using sodium, potassium and other divalent cations such as zinc and copper etc. Therefore all cations which can be bound by phytic acid may be used.

3. Applicant argues that Hansson (US 2,834,678; R2) does not relate to phytase but rather to phosphatase.

a. Since R2 teaches of and uses phytic acid salts (phytin), then the substrate carrying the cations will be a phytate. On the other hand since the enzyme is affecting a

phytate, it can be called a phytase. The functionality of the enzyme used is important not the terminology.

4. Applicant argues that the enzyme used by Hansson is a phosphatase from veal bone and that phytases are not expected in bones because phytate is not present in bone.

a. As long as the phosphatase enzyme disclosed by Hansson can hydrolyze the phytate, it will be necessary and sufficient conditions. There are no requirements in the claims to indicate any source of enzymes.

5. Applicant argues that a literature search has been performed and based on that applicant presents certain references.

a. The references presented by the applicant have been considered and they do not seem to support the patentability of the presently claimed invention.

6. Applicant argues that WO 02/05881 (R3) discloses that a drink or pill containing phytase is used to deliver phytase to humans and that the present invention relates to an altogether concept which comprises phytase and phytates. Further, according to the present invention at least part of the essential cations are bound to phytase.

a. R3 discloses the use of phytase in foods. Foods such as bread, cereals, milk, cheese, yogurt etc. It should be realized that phytase will hydrolyze the phytates which are either naturally present in the food e.g. soymilk or which are added to the foods. Therefore, teachings of R3 is also an "altogether" concept because it involves, phytase, phytates and an improved bioavailability of minerals due to hydrolysis of phytates.

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F 9:00 to 5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Callie E. Shosho/
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